

**REMARKS****STATUS OF CLAIMS**

With this amendment, Claims 1 and 2 are pending in the present application and under examination, Claims 3, 4, 35 and 26 are withdrawn as being directed to non-elected inventions, Claims 5-24 and 27-82 are cancelled, and Claims 83-85 are new.

Claim 1 has been amended to recite “or storing the identified amino acid sequence to a computer storage medium.” Similarly new Claims 83 and 84 recite “outputting the identified amino acid sequence to a user display” and “storing the identified amino acid sequence to a computer storage medium,” respectively. Support for the amendment and new claims can be found throughout the application as filed, for instance in the summary, which teaches that the present invention provides “a computer, a computer memory, a computer storage medium (e.g., floppy disk, fixed disk, CD-ROM, etc.), and/or a computer database” (Specification, page 7, lines 27-29). Further support can be found in Examples 2-10, which set forth multiple amino acid sequences corresponding to the open reading frames identified by the methods of the present invention, and which were clearly stored to a computer storage medium prior to submission of the present application. Lastly, support for new Claim 85, which recites “wherein the putative open reading does not consist of one or more of NMB0427, NMB0428, NMB0429 and NMB0430.” Support for the negative limitation of new Claim 85 can be found but is not limited to the teaching that “the invention provides [a] nucleic acid including a fragment of one or more of the nucleotide sequences set out herein, including the NMB open reading frames shown in Appendix B hereto” (Specification, page 6, lines 6-8). Per the MPEP 2173.05(i): if “alternative elements are positively recited in the specification, they may be explicitly excluded in the claims.” See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) (“[the] specification, having described the whole, necessarily described the part remaining.”). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff’d mem.*, 738 F.2d 453 (Fed. Cir. 1984). Thus the amendments and new claims do not introduce new matter.

Cancellation and amendment of the claims is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications hereof containing the canceled or original claims.

### **OBJECTION OF CLAIM 1**

Claim 1 is objected to as allegedly containing informalities (Office Action, page 2). The Examiner indicates that the conjunction “and” was used after both the second and third steps. Applicants thank the Examiner for pointing out this clerical error, which Applicants hereby correct by deletion of the conjunction after step two. As the amended claims are proper, Applicants respectfully request that this objection be withdrawn.

### **REJECTION OF CLAIMS UNDER 35 U.S.C § 101**

Claims 1 and 2 have been rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter. Specifically, the Examiner asserts that the

instant claims are drawn to [a] computation method for identifying an amino acid sequence. However, as claimed, the method does not produce a tangible result. For example, the method as claimed may take place entirely within the confines of a computer or a human mind without any communication to the outside world and without using or making available for use, the results of the computation. ... This rejection may be overcome by indicating the identified amino acid sequence can be output to a display (Office Action, page 4).

This rejection is respectfully traversed. Even so, as discussed above, Applicants have amended Claim 1 to recite “outputting the identified amino acid sequence to a user display or storing the identified amino acid sequence to a computer storage medium,” in order to facilitate prosecution of this case and without prejudice or disclaimer. As such, both options of step four of the amended claims are directed to a tangible result (e.g., outcomes that are perceptible to a user), namely computer display output and computer file storage, respectively. Since all embodiments of

the claimed invention comprise a tangible result, Applicants respectfully request that this rejection be withdrawn.

### **REJECTION OF CLAIMS UNDER 35 U.S.C. § 103(a)**

Claims 1 and 2 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Ribot (WO 98/17805). Specifically the Examiner contends that the difference between Ribot and the claimed invention “constitutes nonfunctional descriptive material because the content of the nucleic acid database does not alter how the method functions” (Office Action, page 7). This rejection and its supporting remarks are respectfully traversed.

Per the MPEP 2106.01, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works, and a compilation or mere arrangement of data. Applicants respectfully contend that “a computer database comprising the *N. meningitidis* serogroup B strain MC58 genome sequence of SEQ ID NO:1” is “functional descriptive material” as defined by the MPEP. In particular, the organization of nucleotides in SEQ ID NO:1 is not an arbitrary collection of letters, rather Applicants contend that there is a physical and logical relationship between the nucleotides in the sequence, which supports downstream data manipulation functions (e.g., transcription and translation in vitro and in vivo, determination of putative open reading frames and design of PCR primers for amplification thereof). In brief, the genetic blueprint of *N. meningitidis* serogroup B, more closely resemble a queue-type data structure than nonfunctional descriptive material such as music and literature. Accordingly, Applicants urge the Examiner to give the step of providing a computer database comprising the *N. meningitidis* serogroup B strain MC58 genome sequence more weight in his determination of patentability.

Moreover, a comparison of the *N. meningitidis* serogroup B strain MC58 genome sequence of SEQ ID NO:1 as recited in the claims to SEQ ID NO:8 of Ribot (e.g., from related US, 6,472,518) to Ribot) demonstrates that there are multiple differences between the two sequences, which are apparent in all three of the open reading frames disclosed by Ribot (Alignment attached at Tab A). In particular, Applicants identified four open reading frames in the region of the *N. meningitidis* genome examined by both groups, NMB0427 – 1176bp, NMB0428 – 1308bp, NMB0429 – 102bp and NMB0430 – 876bp (See, Specification, Appendix B, page 8). In contrast Ribot identified three open reading frames of dissimilar sizes, ORF1 – 1185bp, ORF2 – 960bp and ORF3 – 457bp (Ribot, SEQ ID NOs: 1, 3 and 6). Thus the *N. meningitidis* genome sequence, the putative open reading frames, and the identified amino acid sequences of the claimed methods differ from the disclosure of Ribot. Additionally, new Claim 86 specifically excludes the putative open reading frames in the region of the *N. meningitidis* genome examined by both groups, providing a further difference between the claimed invention and Ribot. Equally important there is no teaching or suggestion in Ribot (or otherwise known to one having ordinary skill and common sense) that would lead one of skill in the art to arrive at the claimed invention without undue experimentation. Accordingly, since the claimed invention is not obvious in view of Ribot, Applicants respectfully request that this rejection be withdrawn.

### CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding objection and rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **223002100400**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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# **TAB A**